DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 15, 2014

Stabilynx, Incorporated
Mr. Mike Rosenthal
Vice President, Engineering Operations
3475-0 Edison Way
Menlo Park, California 94025

Re: K142643
Trade/Device Name: Stabilynx PEEK Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 15, 2014
Received: September 17, 2014

Dear Mr. Rosenthal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Department of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142643

Device Name
Stabilynx PEEK Suture Anchor

Indications for Use *(Describe)*

The Stabilynx Suture Anchor is a soft tissue anchor which will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as:

• Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Acromio-Clavicular Separation Repair, Capsular Shift/Capsulolabral Reconstruction, Biceps Tendonesis, Deltoid Repair

• Knee: Extra Capsular Repairs (Medial Collateral Ligament, Lateral Collateral Ligament, Posterior Oblique Ligament), Illiotibial Band Tendonesis, Patellar Tendon Repair

• Elbow, Wrist, Hand: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Biceps Tendon Reattachment

• Foot and Ankle: Medial Instability Repair/Reconstruction, Lateral Instability Repair/Reconstruction, Achilles Tendon Repair/Reconstruction, Midfoot Reconstruction, Hallux Valgus Reconstruction

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 6: 510(k) Summary (21 CFR § 807.92(c))

I: SUBMITTER INFORMATION

Submitter: Stabilynx, Inc.
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Menlo Park, CA 94025

Contact: Mike Rosenthal
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Date Summary Prepared: 15 September 2014

II: SUBJECT DEVICE INFORMATION

Device Trade Name: Stabilynx PEEK Suture Anchor
Common Name: Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR §888.3040)
Product Code: MBI

III: PREDICATE DEVICE INFORMATION

Predicate Device: Stryker PEEK Zip Suture Anchor (K070758)

No recalls, market withdrawals or safety alerts were identified in FDA's database for the above referenced predicate device.

No reference devices were used in this submission.

IV: DEVICE DESCRIPTION:

The Stabilynx PEEK Suture Anchor consists of an ethylene oxide sterilized, implantable, poly-ether-ether-ketone (PEEK) bone screw and ultra high molecular weight polyethylene (UHMWPE) suture. The suture anchor is supplied pre-mounted on a disposable Insertion Tool, which consists of a non-patient contact, acrylonitrile butadiene styrene (ABS) handle molded over an externally-communicating, stainless steel shaft. The anchor comes pre-loaded with two (2) high-strength, polyethylene, non-absorbable sutures. The Stabilynx PEEK Suture Anchor design allows a surgeon to create at least one contiguous suture link between one or more adjacent suture anchors after the suture anchors have been inserted into bone. The suture anchor is designed such that one or both of the pre-loaded sutures may be exchanged with one or more sutures connected to an adjacent suture anchor(s).

V. INDICATIONS FOR USE:

The Stabilynx Suture Anchor is a soft tissue anchor which will be used to secure soft tissue to bone during reconstructive surgery. The anchor is intended for use in such procedures as:

- **Shoulder**: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Acromio-Clavicular Separation Repair, Capsular Shift/Capsulolabral Reconstruction, Biceps Tendonesis, Deltoid Repair
- **Knee**: Extra Capsular Repairs (Medial Collateral Ligament, Lateral Collateral Ligament, Posterior Oblique Ligament), Illiotibial Band Tendonesis, Patellar Tendon Repair
- **Elbow, Wrist, Hand**: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Biceps Tendon Reattachment
- **Foot and Ankle**: Medial Instability Repair/Reconstruction, Lateral Instability Repair/Reconstruction, Achilles Tendon Repair/Reconstruction, Midfoot Reconstruction, Hallux Valgus Reconstruction

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The primary technological principle for the subject and predicate devices is to anchor suture to bone so that the suture may be used to secure soft tissue to bone. The subject and predicate devices accomplish this function by similar means. At a high level, the subject and predicate devices are based on the following same technological elements:

- PEEK implantable bone screw and non-absorbable sutures
- Ability to secure soft tissue to bone during reconstructive procedures

The following technological differences exist between the subject and predicate devices:

- Sutures in the subject device contain suture loops at either end
- Suture loops of the subject device enable contiguous linking of adjacent suture anchors

VII. PERFORMANCE DATA:

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Verification tests included: a) Dimensional and Visual Inspections; b) Suture Loop Exchange Force; c) Fixation Strength with and without Cycle Loading; d) Inserter and Anchor Torque Strength; e) Suture Knot-Pull Tensile Strength; and, f) Repair Suture Bifurcated Loop Strength. These tests were conducted on ethylene oxide sterilized units at baseline and on devices subjected to accelerated aging conditions equivalent to three (3) months. Passing results were obtained for all design verification tests.

Biocompatibility Testing

The biocompatibility evaluation for the Stabilynx PEEK Suture Anchor was conducted in accordance with the requirements defined in ISO 10993-1 “Biological Evaluation of Medical Devices” and FDA’s guidance (“Use of International Standard ISO 10993”, draft document issued on 24 April 2013 and BlueBook Memorandum #G95-1 dated 01 May 1995). Testing included the following: 1) Cytotoxicity; and, 2) Systemic Toxicity. The device is comprised of: 1) an inserter shaft that is considered a tissue/bone

contacting component for a duration of < 24 hours; and, 2) a bone anchor and suture that are considered permanent implants.

Sterilization Data

The sterilization parameters for the Stabilynx PEEK Suture Anchor device comply with the requirements prescribed in the applicable standards for ethylene oxide sterilization (ISO 11135-1:2007 "Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices" and ISO 10993-7:2008 "Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals"). The sterilization cycle ensures a SAL of 10^{-6}. The EO and ECH residuals were below the limits specified in the standard.

Packaging and Shipping Validation

Packaging and shipping validation studies were successfully conducted on sterilized Stabilynx PEEK Suture Anchors pursuant to the applicable ASTM guidelines. These tests included seal peel and bubble emission tests at baseline and T= 3 months. Tests were conducted pursuant to ASTM F88 "Standard Test Method for Seal Strength of Flexible Barrier Materials"; and ASTM 2096-11 "Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)". Additionally, the ASTM D4169-09 standard was used to evaluate package performance under simulated transport conditions. All tests results met the acceptance criteria.

VIII CONCLUSIONS:

Based on the technological characteristics, indications for use, and bench performance data provided in this premarket notification, the Stabilynx PEEK Suture Anchor Device has a safety and effectiveness profile that is substantially equivalent to the predicate device. The information included in this 510(k) submission demonstrates the same intended use, similar indications for use and technological characteristics of the Stabilynx PEEK Suture Anchor Device as compared to the predicate device. The differences between the subject and predicate devices do not raise different types of safety or effectiveness questions and the performance data demonstrate substantial equivalence.